

# Commentary I Essentials of good epidemiological practice: are guidelines following guidelines?

*Dr. Erik von Elm is a medical doctor and epidemiologist at the Department of Social and Preventive Medicine, University of Berne, Switzerland. Dr. Matthias Egger is head of the Department of Social and Preventive Medicine, University of Berne, Switzerland and also a visiting professor of clinical epidemiology at University of Bristol, UK*

Pilots are trained to fly aeroplanes, surgeons are trained to operate on patients, but who is trained to conduct epidemiological research? The first two statements are platitudes, the third is a question of genuine concern. Much, if not most, epidemiological research is done by colleagues with little or no formal training in epidemiology. This may be particularly true for Switzerland. Our country, thanks to Bernoulli, may have been ahead of modern epidemiology in the 18<sup>th</sup> century (Dietz & Heesterbeek 2000) but since then the road has been largely downhill, and neither clinical nor population-based epidemiological research have a strong tradition in Switzerland. Indeed, the poor quality of applied clinical research in Switzerland is a matter of current debate (Schweizerischer Wissenschafts- und Technologierat 2002). Against this background, recommendations on essential principles of good epidemiological practice (Altpeter et al. 2004), “written in good faith for the betterment of epidemiology in Switzerland” by the Epidemiology Group of the Swiss Society for Public Health are surely welcome. Or are they?

**What audience, what purpose, what methodology?**  
 Recommendations and guidelines are “systematically developed statements” and several bodies have formulated methods for developing scientifically sound guidelines (Shanefelt 1999). In this commentary we examine to what extent the EGEP guidelines follow guidelines on how to develop guidelines. Table 1 lists eight accepted methodological standards. These were developed in the context of clinical practice guidelines, but are equally helpful when examining methodological and reporting guidelines.

**Table 1** Methodological standards on guideline development

Standard
1. Purpose of the guideline is specified
2. Rationale and importance of the guideline are explained
3. The participants in the guideline development process and their areas of expertise are specified
4. Intended audience or users of the guideline are specified
5. Method of identifying scientific evidence is specified
6. The evidence used is identified by citation and referenced
7. The method by which the guideline underwent external review is specified
8. An expiry date or date of scheduled review is specified

Adapted from Shanefelt et al. (1999)

What is the purpose and intended audience of the EGEP guideline? We do not think that this is well defined at present. Should these recommendations mainly be used by researchers from other disciplines who lack training in epidemiology? In this case, recommendations that essentially consist of a check list (“describe, define, select, ... publish”), with little explanation of the whys and why nots, or on the hows and how nots will be of limited use. For example, the recommendation to analyse the data “beginning with descriptive and proceeding to inferential statistics” and to “determine the possible confounders and effect modifiers” will be of little help to those not familiar with these terms. On the other hand, recommendations such as “define what kind of data are needed to answer the research question” or “plan for the needed time, money, and personnel” are stating the obvious. Other statements are ambiguous to any audience, for example “plan for an analysis

that can handle eventual anomalies in your data". This statement could easily be misunderstood and the EGEP recommendation might be inappropriate, depending on what exactly is meant by "anomalous data".

What can be learned from earlier initiatives? In the case of the Consolidated standards on the reporting of clinical trials (CONSORT) (Moher et al. 2001), the working group not only published the result of its work (i.e., the guidelines), but also an explanatory document (Altman et al. 2001) giving the rationale, background information and relevant examples for each item of the statement. This additional article aimed to make the process of guidelines development more transparent and helped to increase the acceptance of the proposed guidelines. The recent initiative to develop standards of reporting in diagnostic research (STARD) followed a similar strategy (Bossuyt et al. 2003a; 2003b). Unfortunately, the methods of guidelines development are not explained in the case of EGEP. For instance, it remains unclear how the items were selected and what empirical evidence or theoretical considerations underpin that selection.

In addition to a transparent methodological approach to guideline development, it is essential to subject the draft recommendations to review by the epidemiological community, including review by future users. Wide circulation among opinion leaders and intended users, followed by revisions taking comments into account, will improve quality, publicise the effort and broaden ownership. This, and other commentaries accompanying the publication of the EGEP recommendations can be seen as a form of peer review, but this is post-hoc and therefore unsatisfactory.

### What about implementation?

The development of recommendations should be linked to a thoughtful implementation strategy – one of the most consistent findings in research of health services is the gap between evidence and practice (Grol & Grimshaw 2003). Indeed, publishing the EGEP recommendations in an English-language specialist journal will have limited impact. If the authors are serious about the "betterment of epidemiology in Switzerland" then considerable efforts will be needed to explain, promote and implement the EGEP guideline. These efforts should reach beyond the narrow Swiss epidemiological community.

Setting up a dedicated website has been useful for disseminating reporting guidelines (see [www.consort-statement.org](http://www.consort-statement.org)). Experience with clinical practice guidelines demonstrates that changing professional behaviour is difficult, but not impossible (Grimshaw et al. 2004). Various strategies targeting obstacles at different levels are required, and education needs to be interactive and continuous and include discussion of the relevant evidence. Some barriers to change will be associated with the organisation of the research process, resources, leadership and the political environment, and difficult to tackle in the short term.

### Conclusions

The publication of recommendations for good epidemiological practice is a welcome initiative. The current version of this guideline should, however, be seen as a living document, which will evolve over time in order to contribute to improving epidemiological research in Switzerland.

**Erik von Elm and Matthias Egger**

### References

- Altman DG, Schulz KF, Moher D, et al. (2001). The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med* 134: 663–94.
- Altman DG, Schulz KF, Moher D, et al. (2005). Essentials of good epidemiological practice. *Soz Präventiv Med* 50: 12–5.
- Bossuyt PM, Reitsma JB, Bruns DE, et al. (2003a) The STARD statement for reporting studies of diagnostic accuracy: explanation and elaboration. *Clin Chem* 49: 7–18.
- Bossuyt PM, Reitsma JB, Bruns DE, et al. (2003b). Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. *BMJ* 326: 41–4.
- Dietz K, Heesterbeek JA (2000) Bernoulli was ahead of modern epidemiology. *Nature* 408: 513–4.
- Grimshaw JM, Thomas RE, MacLennan G, et al. (2004). Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess* 8(6): iii–iv, 1–72.
- Grol R, Grimshaw J (2003). From best evidence to best practice: effective implementation of change in patients' care. *Lancet* 362: 1225–30.
- Moher D, Schulz KF, Altman DG, for the CONSORT Group (2001). The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomized trials. *Lancet* 357: 1191–4.

Schweizerischer Wissenschafts- und Technologierat (2002). Klinische Forschung in der Schweiz. Bern: Schweizerischer Wissenschafts- und Technologierat.

*Shanefelt TM, Mayo-Smith MF, Rothwangl J* (1999). Are guidelines following guidelines? The methodological quality of clinical practice guidelines in the peer-reviewed medical literature. *JAMA* 281: 1900–5.

---

**Address for correspondence**

**Prof. Matthias Egger**  
**Department of Social**  
**and Preventive Medicine**  
**University of Berne**  
**Finkenhubelweg 11**  
**CH-3012 Berne**  
**e-mail: [egger@ispm.unibe.ch](mailto:egger@ispm.unibe.ch)**



To access this journal online:  
<http://www.birkhauser.ch>

---